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| 09/771,357 | 01/26/2001 | Saraswati Sukumar JHU16 | | 6079 | |
| 28213 7590 07/03/2002 GARY CARY WARE & FRIENDENRICH LLP | | | EXAMINER | | |
| 4365 EXECUT | IVE DRIVE | SOUAYA, JEHANNE E | | | |
| SUITE 1600 | CA 92121-2189 | ART UNIT | PAPER NUMBER | | |
| | | | 1634 | a | |
| | | | DATE MAILED: 07/03/2002 | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| A SHORTENED STATUTORY PERIOD FOR REPLY IS SETTO EXPIRE 1 MONTH(S) FROM THE MALLING DATE OF THIS COMMUNICATION. Extensions of three may be available in the communication. If the period for reply appetition above is lies than thirty (30) days, a reply within the statistion primiting of the reply appetition above, the resonant statistion period will apply and will expect (5) in MOV Pation for reply appetition above, the resonant statistion period will apply and will expect (5) in MOV Pation for reply appetition above, the resonant statistion period will apply and will expect (5) in MOV Pation to be reading than the reply are communication. False to reply within the edit of extent than the reply and the period of reply appetition to expect the maining date of this communication, even if timely fleet, may reduce any examine patient them adjustment. Sea 3 CFR 170(a): Status 1) Responsive to communication(s) filled on 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-37 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) is/are objected to. 8) Claim(s) 1-37 are subject to restriction and/or election requirement. Application Papers 9) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. Sea 37 CFR 1.85(a). 11) The proposed drawing correction filed on is a) approved by isapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action. 12) The coath or declaration is objected to by the Examiner. Priority under 35 U.S.C. § 119 and 120 13) Acknowledgment | · · · · · · · · · · · · · · · · · · · | | Application No. | | Applicant(s) | | | | | |
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| Jehanne Souaya | Office Action Summary | | 09/771,357 | | SUKUMAR ET AL. | | | | | |
| Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ± MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. Estationar for may be serviced under the provisions of 3 CFR 1.13(a). In or evert, however, may a reply be timply field after SIX (S) MONTHS from the mailing date of this communication. If the period from they serviced security to the date communication and the security maintain of the timply field after SIX (S) MONTHS from the mailing date of this communication. If the period may searched security the maintain security period will apply and will expose 12(d) MONTHS from the mailing date of this communication. If the period charge within the security the maintain security in the security minimum of thinky 12(d) days will be considered timely. Failure to reply within the set of extended period for reply will, by statutory period will apply and will expose 12(d) MONTHS from the mailing date of this communication, even if timely flee, may reduce any security of the security of | | | Examiner | | Art Unit | | | | | |
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| THE MALLING DATE OF THIS COMMUNICATION. Esteration of time may be available under the provisions of 3 CPR 1.13(6). In co event, however, may a reply bit timely field after SIX (6) MONTHS from the mailing date of this communication. If the period travely section date is less than through the second travely within the statulory pretrieval within the considered timely. If the period travely section the provision of the communication of the provision of the prov | | | / IS SET TO EXP | RE 1 MONTH(| S) FROM | | | | | |
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| 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6) U Other: | 2) Noti | ce of Draftsperson's Patent Drawing Review (PTO-948) | 4) 5) 6) | | | | | | | |

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I-VIII. Claims 1-34, drawn to methods of determining a predisposition for or diagnosing a cellular proliferative disorder of the breast by detecting the methylation status of patentably distinct nucleic acids, classified in class 435, subclass 6. Wherein each separate group encompasses a single gene. For example, Group I is directed to Twist as well as the primers specific for Twist. Group II is directed to cyclin D2 as well as to primers specific for cyclin D2. Group III is directed to RARB2 as well as the primers specific for RARB2. Group IV is directed to WT1 as well as the primers specific for WT1. Group V is directed to HOXA5 as well as the primrs specific for HOXA5. Group VI is directed to 14.3.3 sigma as well as the primrs specific for 14.3.3 sigma. Group VII is directed to Estrogen receptor as well as the primrs specific for Estrogen receptor. Group VIII is directed to NES-1 as well as the primrs specific for NES-1. Upon election of one of these groups, applicant is required to specify which primers are specific for the method elected. It is further noted that the claims encompass methods involving a combination of the above genes. If applicant wishes to elect such, please specify

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which combination of specific genes for use in the method and the relevant primers.

- IX-XV. Claims 35-37, drawn to kits for detecting a cellular proliferative disorder, classified in class 536, subclass 24.3. Group IX is directed to kits comprising primers specific for Twist. Group X is directed to kits comprising primers specific for cyclin D2. Group XII is directed to kits comprising primers specific for RARB2. Group XII is directed to kits comprising primers specific for WT1. Group XII is directed to kits comprising primers specific for HOXA5. Group XIII is directed to kits comprising primers specific for 14.3.3 sigma. Group XIV is directed to kits comprising primers specific for estrogen receptor. Group XV is directed to kits comprising primers specific for NES-1. It is further noted that the claims encompass kits comprising primers specific for combination of the above genes. If applicant wishes to elect such, please specify the relevant primers.
- 2. The inventions are distinct, each from the other because of the following reasons:

 Inventions IX-XV and I-VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP)

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§ 806.05(h)). In the instant case the nucleic acids of groups IX-XV can be used to express polypeptides.

The inventions of groups I-VIII are patentably distinct from each other because each 3. method involves detecting the methylation pattern of patentably distinct genes which are unrelated. Further, the methods of diagnosing cellular proliferation of the breast using each patentably distinct gene are unobvious over one another. The inventions of Groups IX-XV are patentably distinct from each other because they are directed to nucleic acid sequences that hybridize to patentably distinct genes. Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 USC 121 and 37 CFR 1.141. By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant... to elect that invention to which his claim shall be restricted." 37 CFR 1.142 (a). See also 37 CFR 1.141(a).

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4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

- 5. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II-XV, restriction for examination purposes as indicated is proper.
- 6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
- 7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).
- 8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya

Patent examiner

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6/26/02